

D<sup>3</sup>  
Sub E4  
synthase gene[,] a phytase gene[,] an ADP-glucose pyrophosphorylase gene[,] a starch synthase gene[,] a starch branching enzyme gene; and [or] a sucrose synthase gene, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

### REMARKS

#### **I. Claims in the Case**

Claims 47, 60 and 63-67 have been amended. Claims 2-4 and 47, and 50-67 are currently pending in this case.

#### **II. Provisional Rejection of Claims Under Obviousness-type Double Patenting**

The Action first rejects all the pending claims as unpatentable over various claims of copending application Serial No. 07/508,045. The Examiner takes the position that the '045 case is directed to fertile transgenic maize plants that are said to be patentably indistinct from the subject matter of the claims of the present invention.

It is respectfully submitted that the subject matter of the presently pending claims is patentably distinct from the subject matter of the '045 application. The present claims are directed to novel combinations of selected individual genes introduced into the corn genome. The claimed subject matter indeed represents a novel and nonobvious combination of elements in that there is no teaching or suggestion in the art relied upon by the Examiner to introduce

these particular genes into the corn genome, and no art or teaching relied upon by the Examiner that would motivate one of skill to do so.

Applicants once again point out that the Action fails to base its finding upon a teaching, suggestion or motivation to employ each of the claimed genes -- a prerequisite to a finding of obviousness-type double patenting. *Carmen Industries, Inc. v. Wahl*, 220 U.S.P.Q. 481, 487 (Fed. Cir. 1983); *Mirafi Inc. v. Murphy*, 14 U.S.P.Q. 1337, 1347 (N.C. 1989). To maintain the rejection it must be shown that the subject matter of the later claims is obvious over that of the earlier case, based upon prior art that existed as of the date of invention of the first patent. It is submitted that no such demonstration has been made here.

In the final Action the Examiner has failed to refer to any such art. While Applicants agree that the various particular genes were themselves known in the art, it is Applicants' position that there is no teaching or suggestion that it is desirable to actually introduce these genes into corn *per se*. Without such a teaching as to each of the individual genes -- a suggestion to introduce the individual gene into corn -- no *prima facie* case of obviousness-type double patenting has been made. If the Examiner is aware of any such teaching, he is respectfully requested to make the art of record or introduce an Examiner's affidavit to that effect. see 37 CFR § 1.107(b).

**III. Rejection of Claims 47, 60 and 63-67**  
**Under 35 U.S.C. § 112, Second Paragraph**

Next, the Action rejects 47, 60 and 63-67 Under 35 U.S.C. § 112, second paragraph, with the Action taking the position that these claims are set forth using improper Markush group terminology.

In response, it is again respectfully pointed out that MPEP § 706.03(y) specifically provides for the format employed by Applicants. The Examiner's attention is directed to the page 700-22 of the MPEP, col. 2, lines 15-18, which states that:

... "wherein R is a material selected from the group consisting of ABC and D" is a proper limitation, then "wherein R is ABC or D" shall also be considered proper.

The Examiner responds merely by stating that the "MPEP specifically uses the term 'consisting of' and not the comprising language."

In response, Applicants point out that the Examiner is apparently misreading the MPEP, which states that the phrase "wherein R is ABC or D" is interchangeable for the phrase "wherein R is selected from the group *consisting* of ABC and D." Thus, the MPEP says that one can either employ the "group consisting" approach or the "claim in the alternative" approach.

Nevertheless, in that the scope of the two approaches is identical and both involve a fully open claim format, Applicants are amenable to amending the claims to remove this minor issue from the appeal.

**IV. Provisional Rejection of Claims 1-67 is Obvious  
Over Copending Application Serial No. 07/508,045**

Next, the Action rejects all the pending claims provisionally as obvious over copending application Serial No. 07/508,045.

In response, Applicants agree that the '045 specification is fully enabling for the introduction and expression of any desired gene into corn. However, it is Applicants' position that the present invention represents a novel combination of otherwise old elements. That is, the invention concern genes from non-corn sources placed into the corn genome, and there is

no suggestion or motivation in the art relied upon by the Examiner to put these particular genes into corn. As such, in order to make out a *prima facie* case, the Examiner is required to demonstrate some motivation in the art as to each and every one of the cited genes! It is submitted that no such motivation has been shown by the Examiner on the record, and thus no *prima facie* case has been made.

Furthermore, in Applicants' previous response it was pointed out that Section 103 provides that "obviousness shall not be negated by the manner in which the invention was made." *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). The Examiner did not respond to this argument is the final Action.

In the present instance, none of the presently claimed species are in any way specifically taught or anticipated by the '045 specification -- the '045 specification merely teaches the general technique of cloning genes in corn and gives examples of genes that are not obvious variants of the genes claimed in the present case. There is submitted to be no suggestion or motivation in the art for one of skill to substitute the genes of the present claims for those set forth in the '045 specification.

Lastly, Applicants point out that the PTO has consistently taken the position that the '045 specification is not generically enabling for fertile, transgenic corn, and that evidence of operability of one gene in corn does not support a conclusion that other genes are so operable. This position appears to be contradicted by the position taken here under obviousness-type double patenting in that the PTO has taken the position that '045 is not broadly enabling. See, *e.g.*, *Dewey & Almy Chem. Co. v. Mimex Co.*, 52 U.S.P.Q. 138 (2d Cir 194); *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979) ("References relied upon to support a rejection under 35 U.S.C.

103 must provide an enabling disclosure, *i.e.*, they must place the claimed invention in the possession of the public . . . . An invention is not 'possessed' absent some known or obvious way to make it . . ."). Thus, if the present rejection is maintained, Applicants request clarification as to how the parent specification can be considered non-enabling by the PTO, yet be relied upon for the present obviousness rejection.

## **XII. Rejection of Claims Under 35 U.S.C. § 103 over Goldman**

Next, all of the pending claims are rejected as obvious over Goldman *et al.* in view of what the Examiner states as "Applicants' acknowledged state of the prior art." The Action takes the position that Goldman *et al.* discloses the preparation of fertile transgenic corn.

In response, with respect to most if not all of the species set forth in the currently pending claims of record, Applicants would agree that as of their invention date methods for successfully introducing genes into the corn genome were known. In the pending appeal in related case USSN 07/565,844 (Adams *et al.*), Applicants will continue to take the position that Goldman *et al. per se* is non-enabling. However, in the context of the present case and for the present appeal only, Applicants will agree that techniques were available to those of skill in the for successfully introducing a selected gene into the corn genome. This should in no way be taken as an acquiescence in the Office's position that Goldman *et al.* is enabling, it is merely to allow the present appeal to focus on the issue at hand -- that there is no teaching or motivation to introduce the particular genes specified in the presently pending claims into corn.

It is Applicants' position that the claimed combination of elements in each of the claims -  
- which specify particular heterologous genes introduced into the corn genome -- is a novel

combination. As such, it is incumbent upon the Examiner to identify individual teaching(s) that would suggest the desirability of making each of the claimed combinations. As recently pointed out by the Federal Circuit, in assessing the patentability of a novel combination of otherwise old elements, "[t]he critical inquiry is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." *In re Newell*, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989).

The requirement that examiner's identify such a motivation is a longstanding patent law doctrine, even in biological cases. In the well-known case of *In re Bergel and Stock*, the CCPA stated it thusly:

The mere fact that it is possible to find two isolated disclosures that might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination.

130 U.S.P.Q. 206 (CCPA 1961).

Motivation to combine elements can not be inferred from prior art that merely mentions the existence of one of the elements of the combination. This is the clear meaning of the relevant case law, such as *In re Gordon*, wherein the Federal Circuit stated:

The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.

221 U.S.P.Q. 1125 (Fed. Cir. 1984).

This doctrine has been routinely embraced by the PTO Board of Appeals. For example, in *Ex parte Kranz*, the Board made it clear that examiner's must identify either an explicit motivation, or a "compelling motivation based upon sound scientific principles." 19 U.S.P.Q.2d 1216, 1218 (BPAI 1990). Here, the Examiner has merely taken the position that since

techniques for introducing genes into corn are known, that transgenic corn with any previously known gene is thereby obvious. This is certainly not the "compelling motivation" based upon "sound scientific principles" referred to by the *Kranz* Board, and certainly an insufficient basis for making out a *prima facie* case of obviousness.

For the foregoing reasons, the Examiner is requested to reconsider and withdraw the rejection based upon Goldman *et al.*

#### **XIV. Conclusion**

It is respectfully submitted that the present response is a complete response to the outstanding Action. If the Examiner has any questions, comments or suggestions, a telephone call to the undersigned Applicants' representative is respectfully requested.

  
Respectfully submitted,

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Date: June 12, 1995

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